eruptions, and hemiplegia; and that the devices would help humanity restore itself to normal health, improve respiratory processes and functions, stimulate secretion, improve muscular and general metabolism, stimulate the excretory organs, and assist elimination. The devices would not effect the results nor fulfill the promises of benefit stated and implied. The devices were misbranded in this respect while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for effective treatment of poor circulation, circulatory ailments, sore, aching joints, sagging chin, etc., insomnia, bruises, sprains, fractures, and many other bone and muscle ailments, sagging muscles, varicose veins, arthritis, gangrene, paralysis resulting from polio, bursitis, prostate gland trouble, pain and paralysis of arm and leg after stroke, constipation, and broken ankles; and for preventing malfunctioning of the heart, lungs, liver, and intestines, enabling all to keep in better physical condition, adding years to one's life, and keeping one young without the usual pains and aches, which are the purposes for which the articles were offered in an advertisement in a Boston newspaper disseminated and sponsored by the distributor, Niagara of New England, and orally by a representative of the consignee. The devices were misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: July 21, 1953. Niagara of New England, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the printed matter which accompanied the devices be destroyed and that the devices be released to the claimant.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4228. Adulteration of agaric root (peelings). U. S. v. 3 Bags * * *. (F. D. C. No. 35406. Sample No. 49983–L.)

LIBEL FILED: August 28, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about October 27, 1952, from Missoula, Mont.

PRODUCT: *Agaric root* (peelings). 3 bags, each containing 272 pounds, of the product at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects.

DISPOSITION: September 21, 1953. Default decree of condemnation and destruction.

4229. Adulteration of Private Formula No. 21. U. S. v. 72 Bottles * * *. (F. D. C. No. 35443. Sample No. 62101–L.)

LIBEL FILED: July 29, 1953, Southern District of Iowa.

ALLEGED SHIPMENT: On or about June 10, 1953, from Peoria, Ill.

PRODUCT: 72 6-ounce bottles of *Private Formula No. 21* at Davenport, Iowa.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of mold. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 18, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4230. Action to enjoin and restrain interstate shipment of drugs intended for injection. U. S. v. Milton A. Calesnick (Addison Laboratories). Temporary restraining order entered; order subsequently vacated and dismissed. (Inj. No. 253.)

COMPLAINT FILED: August 14, 1952, Eastern District of Pennsylvania, against Milton A. Calesnick, trading as Addison Laboratories, Philadelphia, Pa.

NATURE OF CHARGE: The complaint alleged that the defendant was engaged in manufacturing and distributing and shipping in interstate commerce various drugs intended for injection into the human body which were adulterated and misbranded as follows:

(a) Adulteration, Section 501 (b), a number of the drugs purported to be and were represented as drugs, the names of which are recognized in official compendia, namely, the United States Pharmacopeia and the National Formulary, and the strength of the drugs differed from, and their quality and purity fell below, the standards set forth in such compendia; Section 501 (c), in the case of a number of the drugs, their strength differed from, and their purity and quality fell below, that which they purported and were represented to possess; and, Section 501 (d) (2), in the case of a number of the drugs, certain substances had been substituted for the drugs.

(b) Misbranding, Section 502 (a), the labeling of a number of the drugs bore false and misleading statements with respect to the nature and quantity of the ingredients contained in the drugs.

The complaint alleged further that the adulterated and misbranded condition of the drugs resulted from deficiencies in the ingredients of the drugs, the presence of ingredients in amounts in excess of those declared on the labels or required by the standards set forth in the official compendia, the substitution of other drugs for the drugs involved, and the presence of viable micro-organisms evidencing an unsterile product. For example, examination of samples from interstate shipments made by the defendant of certain articles of drug for injection, to wit, liver-folic acid-B_{12}, aminophylline, sodium salicylate and iodide with colchicine, and Lynntestro, disclosed that the liver-folic acid-B_{12} contained approximately 7 percent of the declared amount of vitamin B_{12}; that the aminophylline contained theophylline in excess of the amount permitted by the United States Pharmacopeia; that a number of ampuls of the sodium salicylate and iodide with colchicine did not contain the declared ingredients in that aminophylline had been substituted for such ingredients; and that the Lynntestro was not sterile since it contained viable micro-organisms.

The complaint further alleged that the defendant was well aware that his activities were violative of the Act. Inspections were made of the defendant's plant at Philadelphia, Pa., by inspectors of the Food and Drug Administration on May 18 and August 2, 1950, April 19 and November 26, 1951, and June 9, 20, and 23, and July 22, 1952, at which times the defendant was informed of the lack of analytical and sterility controls in the manufacture of drugs and of the confusion and disorder existing in the plant, which would result in errors of composition and labeling, and was warned that such conditions also would result in the drugs being adulterated and misbranded as aforesaid.

*See also No. 4225.

The complaint alleged further that despite the warnings conveyed to the defendant by the plant inspections, the defendant continued to introduce and deliver for introduction into interstate commerce drugs which were adulterated and misbranded as described above.

DISPOSITION: On August 14, 1952, the court entered a temporary restraining order, under which the defendant was temporarily restrained and enjoined from directly or indirectly introducing, or delivering for introduction into interstate commerce, drugs adulterated and misbranded in the manner complained of. On August 20, 1952, pursuant to a stipulation between the Government and the defendant, the court entered an order continuing the temporary restraining order in effect.

On December 21, 1953, upon consideration of a motion from the defendant showing that the drugs being shipped by the defendant were in compliance with the law in that such drugs were being manufactured under proper analytical and sterility controls, the court entered an order vacating the temporary restraining order and dismissing the complaint.

4231. Adulteration and misbranding of Visnico tablets. U. S. v. 110 Bottles, etc. (F. D. C. No. 35410. Sample No. 22865–L.)

LIBEL FILED: August 27, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about May 28, 1953, by the Bonded Laboratories, from Brooklyn, N. Y.

PRODUCT: 110 1,000-tablet bottles and 552 100-tablet bottles of *Visnico tablets* at East Orange, N. J.

LABEL, IN PART: (Bottle) "Pulvoids No. 500 Visnico (with Phenobarbital) Each Pulvoid Contains: * * * Potassium Nitrate 2 grains Sodium Nitrite 1 grain."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 grains of potassium nitrate and 1 grain of sodium nitrite per tablet.

Misbranding, Section 502 (a), the label statements "Potassium Nitrate 2 grains" and "Sodium Nitrite 1 grain" were false and misleading since the article contained less than the declared amounts of such ingredients.

DISPOSITION: October 1, 1953. Default decree of condemnation and destruction.

4232. Adulteration and misbranding of lubricating jelly. U. S. v. 95 Cartoned Tubes * * *. (F. D. C. No. 35448. Sample No. 42752–L.)

LIBEL FILED: August 6, 1953, Northern District of California.

ALLEGED SHIPMENT: On or about May 6, 1953, by the Tablex Co., from New York, N. Y.

PRODUCT: 95 cartoned tubes of lubricating jelly at San Francisco, Calif.

LABEL, IN PART: "A non-greasy water soluble surgical lubricant lens lubricating jelly sterile."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity of the article fell below that which it purported and was represented to possess since it purported to be sterile when, in fact, it was not sterile.

Misbranding, Section 502 (a), the label statement "sterile" was false and misleading as applied to an article which was not sterile.